REMARKS

Reconsideration and allowance of all pending claims is respectfully requested.

I. Status of the Claims

In this Amendment C, independent claims 31 and 89-111 have been canceled, claim 61 has been amended to correct a minor typographical error therein, and claims 135-155 have been added to more particularly claim certain embodiments. Accordingly, claims 28-30, 32-61 and 135-155 are now pending.

Applicants respectfully reserve the right to pursue the subject matter of any canceled claim in a divisional application.

New claims 135-155 are supported, for example, as follows: claim 135 (original claims 28, 33, 34 and paragraph [0037] of the present application); claim 136 (original claim 30), claim 137 (original claim 32); claim 138 (original claim 35); claim 139-143 (original claims 37-43, respectively, as well as paragraph [0037] of the present application); claim 144 (original claim 42); claim 145 (original claim 43); claim 146-148, 150 and 151 (original claims 48-52, respectively); claims 152-154 (original claims 56-58, respectively); and, claims 149 and 155 (paragraph [0043] of the present application).

II. 35 U.S.C. 103(a) Rejection

Reconsideration is requested of the rejection of claims 28-30, 32-54 and 56-61 under 35 U.S.C. §103 as being obvious in view of Dong, et al. (Analytical Letters (1998)) in view of Walt, et al. (U.S. 6,667,159). Reconsideration is further requested of the rejection of claim 55 under 35 U.S.C. §103 as being obvious in view of Dong, et al. in view of Walt, et al. and further the "Pharma Safe" reference.

A. The Claimed Subject Matter

Claim 28, from which all other rejected claims directly or indirectly depend, is directed to a method for evaluating the stability of drug samples when exposed to

various controlled conditions. Specifically, in relevant part, claim 28 is directed to a method comprising:

> providing an array of drug samples;
>
> **simultaneously** exposing a plurality of the drug samples to at least one controlled environmental condition for an exposure period;
>
> **simultaneously** exposing **the** plurality of the drug samples to at least one controlled chemical condition for **the** exposure period; and
>
> evaluating any change of the exposed drug samples.

Accordingly, it is to be noted that the claim method calls for exposing a plurality of samples to at least one controlled environmental condition **and** at least one controlled chemical condition simultaneously, or **at the same time**, for the **same** period of time.

B. The Cited Art

Dong et al. disclose a method wherein a **single sample** of cefadroxil, **or** sodium cefotaximum, **or** cephradine is treated with a sodium hydroxide solution. **After** treatment with the sodium hydroxide solution, the resulting solution is **then** heated. Accordingly, it is to be noted that not only does Dong et al. **fail to disclose or suggest** the exposure of a plurality of drug samples to a controlled chemical or controlled environmental condition at one time, they also clearly **fail to disclose or suggest** exposing even a **single** sample to controlled chemical **and** controlled environmental conditions **at the same time**, for a set duration (i.e., exposure period).

The Office points to Walt et al. for disclosing the use of high throughput screening of multiple drug samples at one time. Notably, however, like Dong et al., Walt et al. **fails to disclose or suggest** subjecting a plurality of samples to controlled chemical **and** controlled environmental conditions **at the same time**. In fact, while Walt

et al. references high throughput screening of multiple drug samples, Walt et al. are actually concerned or focused on a biosensor array for screening or evaluation.

Finally, the Office points to the "Pharma Safe" system brochure for the concept of subjecting multiple samples to controlled humidity, for purpose of evaluating drug degradation. Notably, however, there is no reference to subjecting the samples to controlled chemical conditions. Thus, there is also no reference to simultaneously subjecting multiple samples to controlled chemical and controlled environmental conditions.

C. The Claimed Subject Matter is Not Obvious

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a **clear articulation** of the reasons why the claimed invention would have been obvious. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was **some teaching, suggestion, or motivation**, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at **each and every limitation** of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. Applicants respectfully submit the Office has failed to establish a *prima facie* case of obviousness because each and every element of the claims has not been disclosed or suggested by the cited combination of references, and/or because there is no motivation to modify the references in order to achieve the claimed subject matter.

As noted above, Dong et al. disclose **sequentially** subjecting a single sample to controlled chemical, then controlled environmental, conditions. Assuming, *arguendo*, motivation existed to combine the disclosures of Dong et al. and Walt et al., one of ordinary skill in the art, **at most**, would be motivated to **sequentially** subject multiple

samples to controlled chemical, **and then** controlled environmental, conditions. Accordingly, this cited combination of references **fails to disclose or suggest each and every element** of the claims, because there is simply no suggestion or motivation to **simultaneously** subject multiple samples to controlled chemical **and** controlled environmental conditions. The addition of the Pharma Safe brochure does nothing to change this outcome. Specifically, and again assuming *arguendo*, that motivation existed to combined the disclosure of these references, one of ordinary skill in the art, **at most**, would be motivated to **sequentially** subject multiple samples to controlled chemical, **and then** controlled environmental, conditions.

In view of the foregoing, Applicants respectfully submit that the cited combination of references **fails to disclose or suggest each and every limitation** of the claims. Applicants additionally submit that there is simply **no motivation** to modify the cited references in order to achieve the claimed subject matter, because Dong et al. arguably **teaches away** from the recited simultaneous treatment of multiple samples, because of the sequential approach taken therein. Applicants therefore submit the present rejection is improper, and accordingly request reconsideration and allowance of claim 28.

Inasmuch as claims 29, 30 and 32-61 depend directly or indirectly from claim 28, it is submitted that these claims are patentable over the cited references for at least the same reason as set forth with respect to claim 28, as well as the other requirements recited therein.

III. New Claims 135-155

New claim 135, from which claims 136-154 directly or indirectly depend, is directed to a method for evaluating the stability of drug samples when exposed to various controlled conditions. Specifically, in relevant part, claim 135 is directed to a method comprising:

> providing an array of drug samples;

> simultaneously exposing a plurality of the drug samples to at least one controlled environmental condition for an exposure period;
>
> simultaneously exposing the plurality of the drug samples to at least one controlled chemical condition for an exposure period; and,
>
> evaluating any change of the exposed drug samples;
>
> wherein at least one of the drug samples is exposed to a first controlled chemical condition and at least one other drug sample is exposed to a **second controlled chemical condition of a type different from the first** controlled chemical condition; and, further wherein at least one of the drug samples is exposed to a first controlled environmental condition and at least one other drug sample is exposed to a **second controlled environmental condition of a type different from the first** controlled environmental condition.

As noted in paragraph [0028] on page 9 of the application, controlled chemical conditions may be, for example, acidic, basic, oxidative, or radical producing conditions, while controlled environmental conditions may be, for example, temperature, light exposure, humidity or atmosphere. Claim 135 therefore calls for subjecting at least one sample to one of these types of chemical conditions (e.g., acidic), while **simultaneously** subject another sample to a **different type** of chemical condition (e.g., basic). Claim 135 does not stop there, however. Claim 135 additionally calls for subjecting at least one other sample to one of these types of environmental conditions (e.g., temperature), while **simultaneously** subjecting another sample to a **different type** of environmental condition (e.g., atmosphere).

Notably, **none** of the cited references, **alone or in combination**, disclose or suggest such a method. Specifically, Dong et al. disclose sequentially subjecting individual samples to a **single type** chemical condition (basic), followed by a **single**

type of environmental condition (temperature). Walt et al. does nothing to address the limited disclosure of Dong et al. in this regard. Finally, the Pharma Safe brochure specifically states that "all . . . samples are exposed to identical, repeatable and reproducible conditions."

In view of the foregoing, Applicants respectfully submit that not only do **the cited references**, both alone and **in combination**, **fail to disclose or suggest each and every limitation** of claim 135, the cited references arguably **teach away** from the subject matter of claim 135, because of their emphasis on subjecting samples to the **same** chemical condition (Dong et al.) or environmental condition (Dong et al. or Pharma Safe). Applicants therefore submit claim 135, as well as claims 136-154 depending therefrom, are patentable over the cited combination of references.

Additionally, inasmuch as claim 155 depends indirectly from claim 28, it is submitted that this claim is patentable over the cited references for at least the same reason as set forth above with respect to claim 28, as well as the other requirements recited therein.

CONCLUSION

In view of the foregoing, Applicants request favorable reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge the fee of $ 130.00 for a one-month extension, and any additional fees in connection with this Amendment C, to Deposit Account Number 01-2384 in the name of ARMSTRONG TEASDALE LLP.

Respectfully submitted,

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